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| 09/846,863 | 05/01/2001 | Philip Goelet | 13020-2-D1 | 5388 |

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| EXAMINER | |
|---|---|
| SISSON, BRADLEY L | |
| ART UNIT | PAPER NUMBER |
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DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/846,863 | GOELET ET AL. | |
| | Examiner | Art Unit | |
| | Bradley L. Sisson | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *32-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *May 26, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 25 May 2006 has been entered.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 32-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in

the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

5. For convenience, claims 32, 39, 56 and 59 the only independent claims under consideration on the merits, are reproduced below.

Claim 32 (currently amended): A method for identifying single nucleotide polymorphic sites in a genome of a species of interest, comprising:

(a) isolating a plurality of DNA fragments from the genome of a population of individual representatives of the species of interest, wherein each fragment corresponds to a location of the genome and the fragments are between about 0.1 kb and 10.0 kb;

(b) sequencing the DNA fragments to determine the nucleotide sequences of each fragment, and

(c) comparing the sequence of each fragment to corresponding fragments that correspond to the same location of the genome from other individual representatives of the species of interest to identify single nucleotide polymorphic sites, wherein each single nucleotide polymorphic site is immediately flanked by a 3' and 5' invariant nucleotide sequence and the species of interest is a mammal and the comparison is made among mammals of the same species.

Claim 39 (currently amended): A method for determining allelic frequency at a single nucleotide polymorphic site, comprising:

(a) isolating a plurality of DNA fragments from a population of two or more individual representatives of a species of interest, wherein each fragment corresponds to a location of the genome and the fragments are between about 0.1 kb and 10.0 kb;

(b) sequencing the DNA fragments to determine the nucleotide sequences of each fragment;

(c) comparing the sequence of each fragment to corresponding DNA fragments from different individual representatives of the species of interest and identifying single nucleotide polymorphic sites having at least two alleles, wherein each single nucleotide polymorphic site is immediately flanked by a 3' and 5' invariant nucleotide sequence and the species of interest is a mammal of the same species and the comparison is made among mammals of the same species,

(d) determining the base identity of each allele present in the location of the genome, and

(e) calculating the allelic frequency for each allele by dividing the frequency at which each allele appears in the sample set by the total number of individuals.

Claim 56 (currently amended): A method of determining the likelihood that a horse is or is not an offspring of a putative parent of the same breed, comprising:

a) isolating a plurality of DNA fragments from upper and lower strands of putative offspring horse genomic DNA, the upper and lower strands comprising single nucleotide polymorphic sites that each have an allelic frequency of at least 0.20;

b) isolating a plurality of DNA fragments from upper and lower strands of putative parental horse genomic DNA, the upper and lower strands comprising single nucleotide polymorphic sites that each have an allelic frequency of at least 0.20,

c) identifying the single nucleotide polymorphic sites of the putative parental genomic DNA and the putative offspring genomic DNA by determining the nucleotide base identity at each single nucleotide polymorphic site, wherein each single nucleotide polymorphic site is immediately flanked by a 3' and 5' invariant nucleotide sequence; and

d) comparing single nucleotide polymorphic sites that match between the putative parental genomic DNA and the putative offspring genomic DNA, thereby determining the likelihood that the horse is or is not the offspring of the putative parent.

Claim 59 (new): A method of determining the likelihood that a mammal is or is not an offspring of a putative parent mammal of the same species, comprising:

a) isolating a plurality of DNA fragments from upper and lower strands of putative offspring mammalian genomic DNA, the upper and lower strands comprising

known single nucleotide polymorphic sites that each have an allelic frequency of at least 0.20;

b) isolating a plurality of DNA fragments from upper and lower strands of putative parental mammalian genomic DNA, the upper and lower strands comprising known single nucleotide polymorphic sites that each have an allelic frequency of at least 0.20;

c) identifying the single nucleotide polymorphic sites of the putative parental genomic DNA and the putative offspring genomic DNA by determining the nucleotide base identity at each known single nucleotide polymorphic site, wherein each single nucleotide polymorphic site is immediately flanked by a 3' and 5' invariant nucleotide sequence; and

d) comparing known single nucleotide polymorphic sites that match between the putative parental genomic DNA and the putative offspring genomic DNA, thereby determining the likelihood that the mammal is or is not the offspring of the putative parent mammal.

6. As presently worded, the method of claim 32 has been interpreted as encompassing the identification of an infinite number of single nucleotide polymorphisms in any and all regions of a genome of any mammal. Said method has also been interpreted as fairly encompassing the simultaneous detection and identification of any and all single nucleotide polymorphisms in any and all DNA fragments, where the DNA fragments represent the same, complete, or different segments of genomes of different subspecies and/or variants of any and al mammals. Said claims have also been interpreted as encompassing performing said determination when there does not exist any knowledge of any part of the nucleotide sequence of any or all of the fragments.

7. A review of the disclosure finds the following examples:

Page 45:

**EXAMPLE 1**
DISCOVERY OF EQUINE POLYMORPHISMS

Page 47:

**EXAMPLE 2**
CHARACTERIZATION OF EQUINE POLYMORPHISMS

Page 50:

**EXAMPLE 3**
ALLELIC FREQUENCY ANALYSIS OF EQUINE POLYMORPHISMS IN SMALL POPULATION STUDIES

Page 55:

**EXAMPLE 4**
PARENTAGE TESTING

Page 56:

**EXAMPLE 5**
IDENTITY TESTING

Page 58:

**EXAMPLE 6**
**ANALYSIS OF A HUMAN SNP**

8. Of the six examples provided, none disclose how one would test and evaluate the myriad "species of interest," much less identify said single nucleotide polymorphisms in a simultaneous manner any number of individuals (claims 32, 36-39, and 43-45), or when testing the "smaller" value of 10,000 individuals (limitation of claims 35 and 42).

9. While the specification does present several examples, such are directed to the analysis of but equine and human DNA and then primarily to the analysis of equine DNA as it relates to parentage analysis (Example 4). Said six examples do not provide an adequate written description of the claimed method whereby one would be able to determine any and all single nucleotide polymorphisms in any and all species of mammals. As presently worded, the claimed method fairly encompasses performing the identification when but one strand is sequenced and/or is present in but only one haploid example. Page 47 of the disclosure, however, teaches, "Differences were concluded to be a DNA polymorphism only if the data was available for both strands, and/or present in more than one haploid example among the five horses tested." The specification does not provide an adequate written description of how to practice the full scope of the invention where but one strand is analyzed and/or where the frequency of the polymorphism is less frequent than 1 in 5, be the species human, equine, or non-human primate, dogs, cats, cattle, or sheep, as is recited in claim 48 and 53.

10. Example 1 clearly teaches that equine polymorphisms were identified in the breed of horses known as thoroughbred. The specification has not provided any teaching that polymorphisms found in one breed is also found in another breed, especially when the phenotype

of the breeds is highly divergent, which in turn fairly suggests that the genetic makeup of the two equines is highly dissimilar, e.g., the Lithuanian Heavy Draft and the Noma, where the Lithuanian Heavy Draft was first recognized in 1964, with the Noma originating in the seventeenth century. While both are horses, the existence of one for centuries and the non-existence of the other until a few decades ago speaks to their genetic diversity. The specification fails to provide an adequate written description of how one would recognize and use single nucleotide polymorphisms (SNPs) in one breed to in turn recognize an individual in another breed, much less determine paternity.

11. Clearly, the limited disclosure provided by the specification does not constitute an adequate written description of the full genus of embodiments encompassed by the claims. Such limited disclosure also does not reasonably suggest that applicant was in possession of the claimed invention at the time of filing. Accordingly, and in the absence of convincing evidence to the contrary, claims 32-60 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

*Response to argument*

12. At page 8 of the response of 25 May 2006, in response to the written description rejection of claims, applicant's representative presents argument that *In re Wright* controls as to what is required to "establish a *prima facie* case of non-enablement" (emphasis added).

13. The above argument has not been found persuasive, as the rejection at issue was not that of enablement, but rather, non-fulfillment of the written description requirement. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the

> invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

14. At page 9 of the response argument is advanced as to what conclusions one of skill in the art would have drawn.

15. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

16. For the above reasons, and in the absence of convincing evidence to the contrary, claims 32-50 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

17. Claims 32-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

18. Of the six examples provided, none disclose how one would test and evaluate the myriad "species of interest," much less identify said single nucleotide polymorphisms in a simultaneous manner any number of individuals (claims 32, 36-39, 43-60), or when testing the "smaller" value of 10,000 individuals (limitation of claims 35 and 42).

19. While the specification does present several examples, such are directed to the analysis of but equine and human DNA and then primarily to the analysis of equine DNA as it relates to parentage analysis (Example 4). Said six examples do not enable the identification of mutations in any and all mammalian species of interest.

20. As presently worded, the method of claims 32-47, 49, 50 and 59-60 fairly encompasses the analysis of virtually any mammal. And in the case of claims 32 and 40, virtually an infinite number of individuals can be tested simultaneously and that the reaction comprises DNA fragments from the entire genome of an infinite number of individuals from an infinite number of species of mammals. The six examples provided do not set forth a reproducible procedure whereby one of skill in the art would be able to correctly associate a potential polymorphism with a given sequence when similar sequences are present yet belong to a different species of mammal. Assuming *arguendo* that one of skill in the art would have been able to identify SNPs in any genetic materials found in any "species of interest," a position that the Office does not concede, such is not enough to enable the claimed method in that the specification must also enable the use of the SNPs. As shown above, the claims method is considered to encompass the identification of SNPs in any "species of interest" where said species of interest encompasses all mammalian life forms, including egg-laying monotremes. The method clearly encompassing mutations that are silent as well as non-silent, yet the specification is effectively silent as to how one is to use such mutations in any mammalian species of interest.

21. Claim 46 requires one to use the polymorphism to identify the mammal. The specification does not provide the requisite starting materials, e.g., the polymorphisms that are species specific, much less teach a reproducible procedure where any one of said polymorphisms is used to identify the species. Similarly, the specification fails to set forth a reproducible procedure whereby any human, non-human primate, dog, cat, sheep, cattle or horse would be identified, much less determine the parentage of same.

22. In view of the breadth of scope of the claims, the introduction of new matter into the disclosure, the limited disclosure provided, the unpredictability in the art, claims 32-58 are not enabled by the disclosure. Accordingly, and in the absence of convincing evidence to the contrary, claims 32-60 are rejected under 35 USC, 112, first paragraph, as not being enabled by the disclosure.

*Response to argument*

23. At page 11 argument is presented that the "Examiner's reliance on *Genentech v. Novo Nordisk* (*Genentech*) as analogous to the present case is misplaced."

24. The above argument has been fully considered and has not been found persuasive. As set forth in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
>
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement

> is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

25. As in *Genentech,* Genentech had in their arguments, relied upon what one of skill in the art would have known. As presented above (see paragraphs 14 and 15), such arguments have not been found persuasive towards the withdrawal of the rejection.

26. The claims clearly encompass the simultaneous analysis of nucleic acid samples from virtually any and all manner of mammals, and that the assay is to be conducted in a simultaneous manner, and that parental testing for any of said mammals, not just cats, cattle, sheep, humans, and non-human primates. Like the case of *Genentech*, the specification does not enable the full scope of the claims. While an applicant need not enable each and every embodiment encompassed by the claims, the specification has not set forth even one example, be it prophetic or not, where even one bovine, sheep, non-human primate, cat, dog, etc., has had its DNA evaluated and SNPs identified, that that these SNPs have in turn been used to identify the species, if not parentage.

27. For the above reasons, and in the absence of convincing evidence to the contrary, claims 32-60 are rejected under 35 USC, 112, first paragraph, as not being enabled by the disclosure.

28. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 32-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

30. Said claims are indefinite with respect to what constitutes the metes and bounds of a "single nucleotide polymorphic site." It is noted that page 11, first full paragraph, of the specification provides a non-limiting definition of the term, and that it seeming can comprise one or more nucleotides.

### *Claim Rejections - 35 USC § 103*

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

33. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

34. Claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al.

35. Erlich et al., Figure 1, Table 1, Figure 2 and corresponding legend and Figure 3, teach a method of identifying single nucleotide polymorphic sites in a genome of interest. As seen in Figure 3, at least 18 different DNA sequences were evaluated. Such a showing meets a limitation of claim 33-35 and 40-42.

36. As set forth in the title and abstract, the method comprises the performance of PCR. Accordingly, a limitation of claims 38 and 45 has been met.

37. Erlich et al., page 34, teaches analysis of a human chromosome six. Such a showing meets a limitation of claims 48, 51, 53, 54, and 59.

38. To the degree that claims recite limitations as to the specific size of a test grouping, or of the fragment size or detection means, such limitations are not deemed to rise to the level of a patentable distinction but rather, are the result of routine optimization. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

> Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however,

> changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136.

39. For the above reasons, and in the absence of convincing evidence to the contrary, claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al.

40. Claims 33-35, and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al., as applied to claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 above, and further in view of Fey et al.

41. See above for the basis of the rejection as it pertains to the disclosure of Erlich et al.

42. Fey et al., teach using DNA polymorphisms in identifying parentage, and that the method can be applied to humans, and more broadly to animals and plants (page 821), and the species of each. Fey et al., page 818, teaches using polymorphisms associated with HLA.

43. Accordingly, and in the absence of convincing evidence to the contrary, claims 33-35, and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al., as applied to claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 above, and further in view of Fey et al.

44. In view of the prior art teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the disclosures of Fey et al., with that of Erlich et al., as the application of DNA polymorphisms would have allowed the ordinary artisan to apply the technology to screening of relatedness between species and well as between members of a species, including the identification of parentage. In view of the detailed description provided, and the desire of such technology in the work place, the ordinary artisan would have been highly motivated and would have had a most reasonable expectation of success.

## *Conclusion*

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

47. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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